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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/720,462

11/24/2003

Thomas J. Boyd

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04/29/2008

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EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

04/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/720,462	Applicant(s) BOYD ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on January 7, 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-22 and 24-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-22 and 24-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07 Jan 2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Request for Continued Examination filed January 7, 2008 after Notice of Allowance.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

The information disclosure statement filed January 7, 2008 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claims

Claim Rejections - 35 USC § 112 - Written Description (New Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 30-37, 48 and 55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. The claims recite the term “constituent”.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See, e.g., In re Wilder, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did ‘little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.’) Mere indistinct terms (such as “constituent” used herein), however, may not suffice to meet the written description requirement. The term constituent may encompass numerous of components including water or a polymer. The specification only supports constituents as being a therapeutic or decorative material. In the instant case, Applicant has given examples of constituent as being a therapeutic or decorative material. Applicant does not provide any other examples other than those two categories previously mentioned.

Claim Rejections - 35 USC § 112 – Indefiniteness (New Rejections)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 15, 17, 18, 26, 27, 29-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14, 15, 17, 18, 26, 27 and 29-33 recite the limitation "the film flake" in the first line. Although the independent claim recites the flakes have a film matrix, the claim does not recite the phrase "film flake". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejections)

1) Claims 16-19, 24, 28-32, 34-37, 40-42, 47, 52 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauschild et al. (US 4,440,877).

Hauschild et al. disclose toothpaste compositions comprising functional agglomerated speckles. The speckles comprise 0.1% to 10% of the dentifrice (col. 11, lines 23-28). The speckles comprise ethyl cellulose and a water soluble polymer. Water soluble polymers may include carboxymethyl hydroxyethyl celluloses, starches and hydroxypropyl methyl cellulose (col. 5, lines 28-38). The speckles provide a decorative and aesthetically improved appearance (col. 1, lines 40-43). The functional material is preferably an abrasive such as calcium carbonate (a calcium salt), alumina and silica. Other functional materials include flavorings, colorants and germicides (col. 3, lines 45-60). In regards to the particles being a flake as oppose to a speckle, the speckles are made by compacting the materials and the particle size is of little importance. That being said the speckle may be any shape and because of the compacting of the particles may also be flat making them in a shape of flake (col. 6, lines 42-48). The compositions are clear gels. Transparent polishing agents are used in the dentifrice and

include colloidal silicas and alkali metal aluminosilicate complexes (col. 4, lines 1-13).

The reference differs from the instant claims insofar as it does not disclose the speckles are flakes.

Matters relating to ornamentation only which have no mechanical function cannot be relied upon to patentably distinguish the claimed invention from the prior art. The shape is a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed particle. See MPEP 2144.04. It would have been obvious to one of ordinary skill in the art to have made flake instead of speckles to incorporate into the compositions of the primary reference motivated by the desire to satisfy the preference of one of ordinary skill in the art.

In regards to the amount of flavoring in the speckle, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See MPEP 2144.05.

2) Claims 14, 15, 20-22, 25-27, 38, 39 and 43-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauschild et al. (US 4,440,877) in view of Rajaiah et al. (US 2002/0187108).

The primary reference, Hauschild et al., is discussed above. The reference differs from the instant claims insofar as it does not disclose the functional materials in the speckles are whitening agent, and anticalculus agent, a breath freshening agent or a desensitizing agent.

Rajaiah et al. is used as a general disclosure to disclose components used as therapeutic components in oral compositions. The compositions of the reference may comprise fluoride salts as an anti-carries agent (paragraph 0034), pyrophosphate salts as anti-tartar agents (paragraph 0033), peppermint, whitening agents such as hydrogen peroxide and urea peroxide (paragraph 0040), desensitizing agents such as potassium nitrate (paragraph 0044), triclosan as anti-microbial agent (paragraph 0036), and antioxidants such as vitamin E (paragraph 0041). Stannous fluoride also provides improved breath benefits (paragraph 0035). The reference differs from the instant claims insofar as it does not disclose the agents are in a film flake.

It is prima facie obvious to use a known material based on its suitability for its intended use. See MPEP 2144.07. It would have been obvious to have used the agents as functional materials in the speckles of Hauschild et al. motivated by the desire to use component for the known function as disclosed by Rajaiah and supported by the MPEP.

In regards to the amount of therapeutic agent, such as the whitening agent, in the speckle, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of

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a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See MPEP 2144.05.

Claims 14-22 and 24-55 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612